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DEPARTMENT OF HEALTH AND HUMAN SERVICES

food and Drug Administration

[Docket No. 99D–4809]

Draft Guidance for Industry on Applications Covered by Section 505(b)(2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Applications Covered by Section 505(b)(2)." A section 505(b)(2) application is a new drug application (NDA) for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This draft guidance also provides information on procedures for submitting an application for approval of a change from an approved drug.

DATES: Written comments on the draft guidance may be submitted by ***(insert date 60 days after date of publication in the* Federal Register).** General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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FOR FURTHER INFORMATION CONTACT: Khyati *N.* Roberts, Center for Drug Evaluation and Research (HFD-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Applications Covered by Section 505(b)(2)." Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) describes three types of NDA's: (1) An application that contains full reports of investigations of safety and effectiveness (section 505(b)(l) of the act); (2) an application that contains full reports of investigations of safety and effectiveness but where at least one of those reports required for approval was not conducted by or for the applicant or for which the applicant has not obtained a right of reference (section 505(b)(2) of the act); or (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, as a previously approved product (section 505(j) of the act).

Section 505(b)(2) of the act was added to the act by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman amendments). It explicitly allows FDA to rely, for approval of an NDA, on data not developed by the applicant. Section 505(b)(2) and (j) of the act replaced FDA's paper NDA policy, which had permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post-1962 pioneer drug products (46 FR 27396, May 19, 1981). Enactment of the generic drug approval provision of the Hatch-Waxman amendments ended the need for approvals of duplicate drugs through the paper NDA process. Specifically, section 505(j) of the act allows for approval of duplicates of approved NDA's on the basis of chemistry and bioequivalence data. Section 505(b)(2) of the act allows for approval of applications other than those for duplicate products.

This draft guidance identifies the types of applications that can be submitted under section 505(b)(2) of the act. A section 505(b)(2) application is an NDA submitted under section 505(b)(l) of the act and approved under section 505(c) of the act. This draft guidance also provides further information and amplification of information stated at 21 CFR 314.54.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on section 505(b)(2) applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 30-99
November 30, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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